# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY,	)
Plaintiff,	) Redacted - Public Version
V.	) C.A. No. 21-833-CFC
BECKMAN COULTER, INC.,	
Defendant.	)
	)

# REPORT AND RECOMMENDATION

Pending before the Court are (1) Defendant Beckman Coulter, Inc.'s ("Beckman's") Partial Motion to Dismiss for Failure to State a Claim Pursuant to Fed. R. Civ. P. 12(b)(6) (D.I. 10) and (2) Plaintiff Becton, Dickinson and Company's ("BD's") Motion for a Preliminary Injunction (D.I. 17). As announced from the bench on January 10, 2022, I recommend that the Court DENY both motions without prejudice to Beckman's ability to raise its 35 U.S.C. § 101 arguments at the summary judgment stage.

#### I. LEGAL STANDARDS

#### A. Motion to Dismiss for Failure to State a Claim

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). A possibility of relief is not enough. *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of

the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 550 U.S. at 557).

In determining the sufficiency of the complaint, I must assume all "well-pleaded facts" are true but need not assume the truth of legal conclusions. *Id.* at 679. "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (internal quotation marks omitted).

# B. Patent Eligibility Under 35 U.S.C. § 101

Section 101 defines the categories of subject matter that are patent eligible. It provides:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court has recognized three exceptions to the broad statutory categories of patent-eligible subject matter: "laws of nature, natural phenomena, and abstract ideas" are not patent-eligible. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). "Whether a claim recites patent-eligible subject matter is a question of law which may contain disputes over underlying facts." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1368 (Fed. Cir. 2018).

The Supreme Court has established a two-step test for determining whether patent claims are invalid under 35 U.S.C. § 101. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208 (2014). In step one, the court must "determine whether the claims at issue are directed to a patent-ineligible concept." *Id.* at 218. This first step requires the court to "examine the 'focus' of the claim, i.e., its 'character as a whole,' in order to determine whether the claim is directed to" an ineligible concept. *Epic IP LLC v. Backblaze, Inc.*, 351 F. Supp. 3d 733, 736 (D. Del. 2018) (Bryson, J.) (quoting *SAP* 

Am., Inc. v. InvestPic, LLC, 898 F.3d 1161, 1167 (Fed. Cir. 2018); Internet Pats. Corp. v. Active Network, Inc., 790 F.3d 1343, 1346 (Fed. Cir. 2015)).

Because "all inventions . . . embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 71 (2012), "courts 'must be careful to avoid oversimplifying the claims' by looking at them generally and failing to account for the specific requirements of the claims." *McRO v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313 (Fed. Cir. 2016) (quoting *In re TLI Commc 'ns LLC Pat. Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016)); *see also Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337 (Fed. Cir. 2016) ("[D]escribing the claims at [too] high [a] level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule."). "At step one, therefore, it is not enough to merely identify a patent-ineligible concept underlying the claim; [the court] must determine whether that patent-ineligible concept is what the claim is 'directed to." *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016). If the claims are not directed to a patent-ineligible concept, then the claims are patent-eligible under § 101 and the analysis is over. If, however, the claims are directed to a patent-ineligible concept, then the analysis proceeds to step two.

At step two, the court "consider[s] the elements of each claim both individually and as an ordered combination" to determine if there is an "inventive concept—i.e., an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Alice*, 573 U.S. at 217-18 (internal quotations and citations omitted). "It is well-settled that mere recitation of concrete, tangible components is insufficient to confer patent eligibility to an otherwise abstract idea." *TLI Commc'ns*, 823 F.3d at 613. Thus, "[m]erely reciting the use of a generic computer or adding the

words 'apply it with a computer" does not transform a patent-ineligible concept into patent eligible subject matter. *Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1338 (Fed. Cir. 2017) (quoting *Alice*, 573 U.S. at 223). Nor is there an inventive concept when the claims "[s]imply append[] conventional steps, specified at a high level of generality" to a patent-ineligible concept. *Alice*, 573 U.S. at 222.

Conversely, claims pass muster at step two when they "involve more than performance of well-understood, routine, and conventional activities previously known to the industry." *Berkheimer*, 881 F.3d at 1367 (citation and internal marks omitted). "The mere fact that something is disclosed in a piece of prior art... does not mean it was well-understood, routine, and conventional." *Id.* at 1369. Moreover, "an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces." *Bascom Glob. Internet Servs., Inc.* v. *AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016). Whether an activity was well-understood, routine, or conventional to a person of ordinary skill in the art is a question of fact. *Berkheimer*, 881 F.3d at 1368.

# C. Preliminary Injunction

A preliminary injunction is "extraordinary" relief. Winter v. Nat'l Res. Def. Council, Inc., 555 U.S. 7, 24 (2008); Kos Pharms., Inc. v. Andrx Corp., 369 F.3d 700, 708 (3d Cir. 2004) ("Preliminary injunctive relief is 'an extraordinary remedy' and 'should be granted only in limited circumstances.") (quoting AT&T Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1427 (3d Cir. 1994)); Intel Corp. v. ULSI Sys. Tech., Inc., 995 F.2d 1566, 1568 (Fed. Cir. 1993) ("[A] preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted."). To obtain a preliminary injunction, the movant has the burden to demonstrate (1) a likelihood of success on the merits, (2) a likelihood of irreparable harm if an injunction is not granted, (3) that the balance of equities tips in the movant's favor, and (4) that an injunction is in 4

the public interest. *See Winter*, 555 U.S. at 20; *K.A. ex rel. Ayers v. Pocono Mountain Sch. Dist.*, 710 F.3d 99, 105 (3d Cir. 2013); *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009).

To demonstrate a likelihood of success on the merits (factor (1)) in a patent infringement case, the patentee must show that it is "more likely than not" to succeed in establishing infringement. Revision Mil., Inc. v. Balboa Mfg. Co., 700 F.3d 524, 526 (Fed. Cir. 2012) ("[T]he estimated likelihood of success in establishing [patent] infringement is governed by Federal Circuit law"). If the patentee fails to make that showing, the court cannot issue a preliminary injunction. Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, i.e., likelihood of success on the merits and irreparable harm."); NutraSweet Co. v. Vit-Mar Enterprises, Inc., 176 F.3d 151, 153 (3d Cir. 1999) ("A plaintiff's failure to establish any element in its favor renders a preliminary injunction inappropriate.").

# II. DISCUSSION

My report and recommendation on the pending motions was announced from the bench as follows:

This is my Report and Recommendation on Defendant Beckman's partial motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6) and BD's motion for a preliminary injunction.

I will summarize the reasons for my recommendations in a moment. But before I do, I want to be clear that my failure to address a particular argument advanced by a party does not mean that I did not consider it. We have carefully considered all of the arguments made by both sides. We will not be issuing a separate written report, but we will issue a written document incorporating the recommendations that I am about to make.

The relevant procedural history is as follows. BD filed this suit for patent infringement on June 7, 2021. BD filed an Amended Complaint on July 21, 2021.

The amended complaint alleges that certain of Beckman's CytoFLEX Cytometer products infringe four of BD's patents. <sup>1</sup> The motions we are discussing today implicate only two of those patents: the '197 patent and the '875 patent.

On July 29, 2021, Beckman filed a partial motion to dismiss for failure to state a claim. (D.I. 10.) Beckman asserts that the '197 patent is invalid under § 101 because its claims are directed to ineligible subject matter. That motion is fully briefed. (D.I. 11; D.I. 12; D.I. 15; D.I. 27.) The parties did not request oral argument.

On August 23, 2021, BD filed a motion for a preliminary injunction to stop Beckman from selling CytoFLEX SRT Benchtop Cell Sorters that are alleged to use technology claimed in BD's '875 patent. (D.I. 17.) The parties stipulated to an extended briefing schedule on the PI motion, which resulted in BD not filing its reply brief until December 20, 2021. On January 3, 2022, Beckman filed a motion for leave to file a sur-reply, which the Court granted on January 5, 2022. Briefing on the PI motion is now complete. (D.I. 18; D.I. 19; D.I. 20; D.I. 21; D.I. 22; D.I. 23; D.I. 24; D.I. 46; D.I. 47; D.I. 48; D.I. 49; D.I. 50; D.I. 51; D.I. 52; D.I. 71; D.I. 72; D.I. 73; D.I. 74; D.I. 75; D.I. 87; D.I. 89.) The Court heard oral argument on January 7, 2022.<sup>2</sup>

I will start with Beckman's partial motion to dismiss based on § 101. (D.I. 10.) Having carefully reviewed and considered the papers submitted by the parties, I recommend that the Court deny the motion without prejudice to Beckman's ability to renew its § 101 arguments at the summary judgment stage. . . .

The '197 patent has 13 claims. Claims 1, 5, and 6 are independent. Beckman says that all 13 claims are directed to unpatentable subject matter. There appears to be a threshold dispute between the parties about whether it is appropriate to treat claim 1

<sup>&</sup>lt;sup>1</sup> U.S. Patent Nos. 6,683,314, 7,129,505, 7,201,875, and 7,787,197.

<sup>&</sup>lt;sup>2</sup> ("Tr. \_\_.)

as representative of all 13 claims.<sup>3</sup> Beckman's opening brief contended that claim 1 is representative; BD says it's not.

BD has raised arguments as to the patentability of each of the claims. Accordingly, it would be inappropriate to conclude that all of the claims are unpatentable simply because claim 1 is unpatentable. However, because Beckman contends that claim 1 is representative, and because I reject Beckman's arguments regarding claim 1, Beckman's motion should be denied and the Court need not consider the remaining claims at this stage.

Neither side has identified any claim construction dispute that needs to be resolved before the Court can assess the § 101 issue. The Court will now proceed to dance the *Alice* two-step.

The Court is directed at step one to examine the focus of the claim to determine whether the claim is directed to a patent-ineligible concept. [Claim 1 reads as follows:

- 1. An optical analyzer comprising:
- (a) a light source adapted to emit an approximately collimated light beam along a light path;
- (b) a focusing lens positioned in the light path, adapted to focus the light beam onto a focal spot within a sample analysis region, wherein said focusing lens has a focal length  $f_1$ ,
- (c) beam-adjusting optics positioned in the light path between the light source and the focusing lens, wherein said beam-adjusting optics comprises at least one beam-adjusting lens that is mounted in a positioning device that allows movement of the beam-adjusting lens in a plane perpendicular to the light path, wherein said beam-adjusting lens has a focal length f₂, wherein said beam-adjusting lens and said focusing lens are separated by a distance z along the light path, and wherein |f₂-z|≥4·f₁.]

<sup>&</sup>lt;sup>3</sup> "Courts may treat a claim as representative in certain situations, such as if the patentee does not present any meaningful argument for the distinctive significance of any claim limitations not found in the representative claim or if the parties agree to treat a claim as representative." *Berkheimer*, 881 F.3d at 1365. "A claim is not representative simply because it is an independent claim." *Id*.

Beckman says that claim 1 is directed either to the natural law of demagnification or to the abstract idea of the claimed formula  $|f_2-z| \ge 4 \cdot f_1$ .

I don't think it's seriously disputed that the claimed apparatus takes advantage of the natural law of demagnification. And it is also true that the claim sets forth a mathematical relationship that restricts the possible focal lengths of the lenses and the possible distance between them.

However, under longstanding Supreme Court precedent, such a tangible apparatus can be patentable subject matter notwithstanding the fact that it may invoke a mathematical equation, a natural law, or a scientific principle. As the Supreme Court stated in the *Mackay Radio* case in 1939, "[w]hile a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."<sup>4</sup>

Of course, the fact that a claim is an apparatus claim that recites tangible components is not dispositive of its patent-eligibility either, as the Federal Circuit recently reaffirmed in the *Yu* case.<sup>5</sup>

Accordingly, I have looked at claim 1 and examined its character as a whole, and I have considered it in light of the specification. Having done so, the claim appears to me to be directed toward an apparatus that has tangible parts, including a light source, a focusing lens, and a beam adjusting lens that sits between the light source and the focusing lens. The position of the beam adjusting lens can be moved in a plane perpendicular to the light path with a positioning device that results in movement of the focal spot of the light beam within a sample analysis region.

The claims do set forth a mathematical relationship that basically requires the beam-adjusting lens to have a long focal length relative to the distance between the lenses and the focal length of the focusing lens. But no one is saying that the claimed relationship is itself "the law of demagnification." Nor am I persuaded that the claim as a whole is otherwise "directed to" the natural law of demagnification.

<sup>&</sup>lt;sup>4</sup> Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86, 94 (1939).

<sup>&</sup>lt;sup>5</sup> Yu v. Apple Inc., 1 F.4th 1040, 1043 (Fed. Cir. 2021) (holding that a claim to an "improved digital camera" with an "image sensor" and "lenses" was nonetheless directed to an "abstract idea").

Rather, I fear that Beckman has done what the Federal Circuit has cautioned against—its proposed description of the focus of claim 1 is at too high a level of abstraction and untethered from the language of the claim.<sup>6</sup>

Again, claim 1 requires tangible elements arranged in a particular configuration. At this point in the case, and on this current record, I am not persuaded that Beckman's articulation of the claim being directed to the natural law of demagnification adequately captures the substance of the claim.

Beckman alternatively says that claim 1 is directed to the abstract idea of the mathematical formula set forth in the claim:  $|f_2-z| \ge 4 \cdot f_1$ . I reject that argument for the same reason. Here, again, I do not think that Beckman's proposed abstract idea sufficiently captures the substance of the claim, which refers to particular tangible elements arranged in a particular configuration.

In sum, at this point in the case I am not persuaded that claim 1 is directed to the natural law or the abstract idea proffered by Beckman. Because I am not persuaded at step one, the Court need not address *Alice* step two.

It may be, however, that claim 1 or the other claims are directed to some other patent-ineligible concept yet to be articulated. Accordingly, I recommend that the Court deny Beckman's motion to dismiss with leave to renew its § 101 arguments at the summary judgment stage.<sup>7</sup>

<sup>&</sup>lt;sup>6</sup> See Enfish, 822 F.3d at 1337; see also McRO, 837 F.3d at 1313.

<sup>&</sup>lt;sup>7</sup> See APS Tech., Inc. v. Vertex Downhole, Inc., No. 19-1166-MN, 2020 WL 4346700, at \*6 (D. Del. July 29, 2020); Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC, No. 17-1390-LPS-CJB, 2019 WL 4466766, at \*10 (D. Del. Sept. 18, 2019), report and recommendation adopted, 2020 WL 1527321 (D. Del. Mar. 31, 2020); Wildcat Licensing WI LLC v. Faurecia S.A., No. 19-839-MN-JLH, 2019 WL 7067090, at \*5 (D. Del. Dec. 23, 2019), report and recommendation adopted, 2020 WL 95481 (D. Del. Jan. 8, 2020) (denying motion to dismiss when the defendants' purported abstract idea failed to satisfactorily capture the substance of the claims); Mod Stack LLC v. Aculab, Inc., No. 18-332-CFC, 2019 WL 3532185, at \*4 (D. Del. Aug. 2, 2019) (denying § 101 motion to dismiss when the defendant's articulation of the abstract idea was oversimplified); 3G Licensing, S.A. v. HTC Corp., No. 17-83-LPS, 2019 WL 2904670, at \*2 (D. Del. July 5, 2019) ("While it may be possible that claim 1 could be accurately characterized as directed to some abstract idea, all I need to decide today [at the motion to dismiss stage] is that the claim is not directed to the abstract idea articulated by defendant."); Groove Digital, Inc. v. Jam City, Inc., No. 18-1331-RGA, 2019 WL 351254, at \*3 (D. Del. Jan. 29, 2019) (denying motion to

I will now turn to BD's motion for a preliminary injunction. (D.I. 17.) I have reviewed all of the papers filed in connection with the motion. We also heard a lengthy oral argument on January 7, 2022. All of the parties' arguments have been carefully considered. For the reasons I will discuss, Plaintiff's request for a preliminary injunction should be denied. . . .

BD's motion concerns only the '875 patent. The patent is titled "Fixed Mounted Sorting Cuvette with User Replaceable Nozzle." The patent relates to a scientific technique called flow cytometry. The inventors of the '875 patent didn't invent flow cytometry. That has been around for a long time. Rather, the specification discloses a flow cytometer having a particular configuration that is alleged to be advantageous because it requires less calibration and alignment.<sup>8</sup>

The '875 patent has 26 claims. Claims 1 and 13 are independent. [Claim 1 recites:

1. A flow cell for use with a flow cytometer comprising: A flow cell body;

A sample delivery tube extending into said flow cell body; At least one sheath flow port on said flow cell body, said at least one port allowing introduction of a flow of sheath flow liquid through said flow cell body;

A cuvette having flat sides and a rectangular cross-section, joined to the flow cell body;

A channel extending through the cuvette, said channel comprising an initial end and a terminal end, wherein liquid from said sample delivery tube and said at least one sheath flow port flows into said initial end of said channel; and

A removable nozzle at said terminal end of said channel through which said liquid from said sample delivery tube and said at least one sheath flow port flows out of said channel, wherein said removable nozzle is positioned on a removable nozzle key having hard planar surfaces on a top and on at least two sides, said nozzle held in a registered position on said flow cell, said registered position at a defined three-dimensional position and at a registered rotational

dismiss under § 101 without prejudice to renew argument at later stage, when the defendant's proposed abstract idea "d[id] not satisfactorily capture the substance of the claims").

<sup>&</sup>lt;sup>8</sup> (See, e.g., '875 patent, 2:59-3:3; 6:19-28.)

orientation, wherein said nozzle is held in said registered position by contact between said hard planar surfaces of said nozzle key and said cuvette.]

Claim 13 is similar to claim 1. It likewise requires, among other things, "a removable nozzle [positioned on a removable nozzle key having hard planar surfaces on a top and on at least two sides, said nozzle held in a registered position . . . at a defined three-dimensional position and at a registered rotational orientation, wherein said nozzle is held in said registered position by contact between said hard planar surfaces of said nozzle key and said cuvette]."

The specification explains why the disclosed configuration is advantageous[:]

In the present invention, significant advantage is derived from a configuration in which a number of the optical elements may be fixed with respect to the flow cell. This advantage arises from the extent of directional stability afforded by the nozzle, which the user may remove and replace and which is selfaligning. The nozzle is insertable in the flow cuvette at a location where the nozzle is registered in place. This registration allows the nozzle to be inserted and positioned such that the nozzle is constrained both as to translation and rotation. Because only the nozzle is movable, the flow cell may be fixed, and does not need to be positioned on a stage that may be angularly or directionally repositioned. As a result, no removal or replacement of the flow cell is required and the user will not have to adjust or realign the flow cell assembly to align the stream of droplets with a required direction for sorting.

Because the flow cell and flow channel never need to be moved, the other optical elements that must be focused or positioned relative to the flow cell now may be fixed as well].<sup>9</sup>

In 2003, BD launched the FACSAria I sorter, which BD says was the first product to practice the '875 patent.  $^{10}$  Since then, BD

<sup>&</sup>lt;sup>9</sup> ('875 patent, 8:54-9:5.)

 $<sup>^{10}</sup>$  (D.I. 19 (First Bell Decl.) ¶¶ 15-16, 21; D.I. 20 (First Chalmers Decl.) ¶¶ 30, 38.)

has introduced several other sorters.<sup>11</sup> In March 2021, Beckman commercially launched its CytoFLEX SRT cell sorter.<sup>12</sup> BD contends that Beckman's CytoFLEX SRT cell sorter infringes the '875 patent and it seeks a preliminary injunction to stop Beckman from selling it.

To obtain a preliminary injunction, the movant must demonstrate, among other things, a likelihood of success on the merits. That includes the requirement that a patentee show a likelihood of proving infringement.<sup>13</sup> To assess whether the [patentee] is likely to establish infringement, the Court [first] must determine the meaning and scope of the asserted claims and second must compare the accused product to the construed claims.<sup>14</sup>

Beckman says that BD is unlikely to show that Beckman's product meets the requirements of the "removable nozzle" limitation. I agree.

All of the '875 patent claims require "a removable nozzle... positioned on a removable nozzle key having hard planar surfaces on a top and on at least two sides, said nozzle held in a registered position . . . at a defined three-dimensional position and at a registered rotational orientation, wherein said nozzle is held in said registered position by contact between said hard planar surfaces of said nozzle key and said cuvette."

BD's theory as to how Beckman's product meets that limitation changed over the course of the briefing. BD's opening brief referred to the first declaration of its expert, Dr. Chalmers. Dr. Chalmers had not examined a physical version of the accused device at the time of his first declaration. His initial opinion was based on his examination of product literature and other publicly-available information. In his initial declaration, he stated that "[t]he three-dimensional position and rotational orientation of the nozzle [in the accused device] are defined by contact between the hard planar surfaces of the nozzle holder and the cuvette. In particular, the hard planar top and sides of the nozzle key (as illustrated [in

 $<sup>^{11}</sup>$  (D.I. 19 ¶ 21.)

 $<sup>^{12}</sup>$  (*Id.* ¶ 22.)

<sup>&</sup>lt;sup>13</sup> Metalcraft of Mayville, Inc. v. The Toro Co., 848 F.3d 1358, 1364 (Fed. Cir. 2017).

<sup>&</sup>lt;sup>14</sup> See Myco Indus., Inc. v. BlephEx, LLC, 955 F.3d 1, 13 (Fed. Cir. 2020).

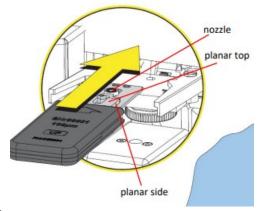
<sup>&</sup>lt;sup>15</sup> (D.I. 18 at 14 (citing D.I. 20 ¶¶ 63-127).)

paragraph 90 of his declaration]<sup>16</sup>) are raised to the height of the nozzle and interface with the cuvette when the nozzle key is locked in position."17

Neither Dr. Chalmers's declaration nor BD's opening brief suggested that any claim construction of the term "contact" was necessary. Nor did they suggest that contact meant anything other than touching, as Dr. Chalmers's declaration appeared to suggest that the surfaces he identified were in fact touching the cuvette.

Beckman's answering brief pointed out that the particular surfaces identified by Dr. Chalmers in his initial declaration were not in fact touching the cuvette. Beckman referred to the declaration of its expert, Dr. Slocum, who performed a physical inspection of the accused device and concluded the same. 18

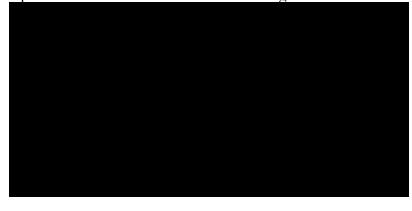
<sup>&</sup>lt;sup>16</sup> The referenced illustration is set forth below:



(D.I. 20 ¶ 90.)

 $^{17}$  (*Id.* ¶ 91.)

<sup>18</sup> (D.I. 46 at 9-10 (citing D.I. 49 (Slocum Decl.) ¶¶ 45-46, 50-55).) Dr. Slocum stated that his physical inspection was consistent with the following illustration:



(D.I. 49 at  $\P$  55.)

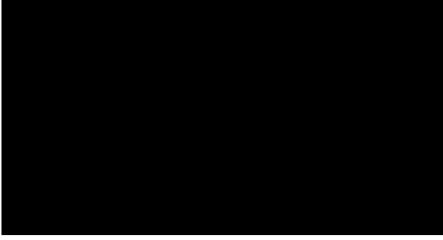
Beckman's answering brief also contended that the CytoFLEX SRT nozzle holder does not touch the cuvette at all, again pointing to Dr. Slocum's declaration. Having inspected the accused device, Dr. Slocum opined that the nozzle and O-ring form a seal with the bottom of the cuvette but that the nozzle holder did not touch the cuvette. <sup>19</sup>

Beckman's answering brief further contended that the accused nozzle was not held in position "by contact" between two hard planar sides of the nozzle holder and the cuvette. Rather, Dr. Slocum explained that the nozzle in the accused device is held in position by contact between the cylindrical surface of the nozzle and a different V-shaped metal component referred to as a "V-groove." The configuration is illustrated in Figure 3 of Dr. Slocum's declaration. <sup>21</sup>

In sum, Dr. Slocum opined that the nozzle in the accused device is positioned by line contacts between the curved surface of the nozzle and the V-groove and is further positioned in the axial direction by an interface between the nozzle and the cuvette.<sup>22</sup>

That brings us to BD's reply brief. BD's reply brief set forth new contentions as to which components on the accused device

<sup>&</sup>lt;sup>21</sup> As shown here:



<sup>(</sup>D.I. 49 ¶ 52, Fig. 3.)

 $<sup>^{19}</sup>$  (See, e.g., D.I. 49  $\P\P$  45-46, 53; see also n. 18, supra.)

<sup>&</sup>lt;sup>20</sup> (D.I. 49 ¶¶ 50-53.)

<sup>&</sup>lt;sup>22</sup> (*Id.* ¶ 53.)

constituted the planar top and side surfaces.<sup>23</sup> Accompanying BD's reply brief was a second declaration by Dr. Chalmers.<sup>24</sup> Dr. Chalmers's second declaration opined that the claimed planar top surface is met by the surface on top of the nozzle in the accused device, which is in contact with the cuvette.<sup>25</sup>

He also set forth a new contention as to what surfaces in the accused device constituted the claimed planar side surfaces. Dr. Chalmers did not opine, however, that the side surfaces he pointed to are touching the cuvette. Rather, those surfaces touch, if anything, the flow cell base. Of course, the claim language requires "contact between said hard planar surfaces of said nozzle key and said cuvette." Dr. Chalmers opined that the contact requirement is nevertheless met because there is a "kinematic chain" between the flow cell base and the cuvette. Implicit in his opinion is his view that contact between two physical components, as it's used in the claims, does not require touching.

Further, Dr. Chalmers did not opine that the surfaces of the nozzle holder alleged to be the side planar surfaces are contacting the flow cell base at the same time. He explained, "[i]f the nozzle holder moves in one direction, the left planar side will make contact with the left wall of the flow cell base, preventing further movement in one direction. And if the nozzle holder is moved in the other direction, the right planar side will make contact with the right wall of the flow cell base, preventing further movement in the other direction." And he acknowledged that there is a "tolerance"—i.e., a gap—between the sides of the nozzle holder and the flow cell base,

<sup>&</sup>lt;sup>23</sup> (D.I. 71 at 9-10.)

<sup>&</sup>lt;sup>24</sup> (D.I. 73.)

 $<sup>^{25}</sup>$  (*Id.* ¶¶ 63-65.)

 $<sup>^{26}</sup>$  (*Id.* ¶ 69.)

<sup>&</sup>lt;sup>27</sup> When I asked BD's counsel at oral argument for a proposed construction of "contact," he proffered the following definition: "contact can be either direct or indirect." (Tr. 19.)

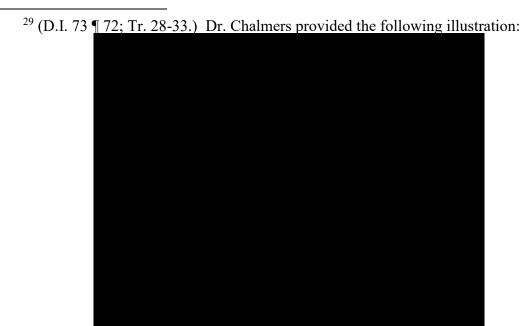
<sup>&</sup>lt;sup>28</sup> (D.I. 73 ¶ 74.)

as illustrated in paragraph 72 of his second declaration.<sup>29</sup> Dr. Chalmers did not measure what the "tolerance" is.<sup>30</sup>

Beckman filed a motion for leave to file a sur-reply, which I granted because I concluded that BD had not only changed its infringement theory, it had also adopted a construction of "contact" that could not have been anticipated from its opening brief.<sup>31</sup>

I have carefully reviewed the entire record before the Court. I cannot conclude on this record that BD is likely to succeed in showing that Beckman's product meets the removable nozzle claim requirements. As an initial matter, I will assume, for purposes of the argument only, that BD is correct that the top surface of the nozzle meets the requirement that the nozzle key have a top hard planar surface that contacts the cuvette. Even if that were true, I am not on this record persuaded that BD is likely to succeed in showing that the accused device has two planar sides that contact the cuvette and, along with the top contact, hold the nozzle in a registered three-dimensional and rotational position.

First, I am not persuaded that the side planar surfaces pointed to by BD contact the cuvette. BD does not contend that those



(D.I. 73 ¶ 72.)

<sup>&</sup>lt;sup>30</sup> (Tr. 30.)

<sup>&</sup>lt;sup>31</sup> (D.I. 78; D.I. 85; D.I. 87; D.I. 89.)

surfaces actually touch the cuvette, and the record evidences that they do not.

Thus, in order for BD to ultimately succeed in showing infringement, it must obtain a claim construction of contact that does not require touching.<sup>32</sup> At the preliminary injunction stage, the Court is permitted to resolve claim construction disputes with "preliminary" or "rolling" claim construction rulings.<sup>33</sup> My recommendation is that, for purposes of the PI motion, the Court reject a construction of contact that does not require touching. The word contact is not a technical term. When used to describe the relationship between two physical objects in space, it is commonly understood to mean touching.<sup>34</sup>

BD cites the *Bradford* case, but that case construed the phrase "coupled to."<sup>35</sup> I am not persuaded that the *Bradford* case has any bearing on the proper construction of "contact."

BD does not suggest that contact has some special meaning in the field of flow cytometry generally. Rather, BD contends that requiring contact to mean touching would read out the preferred embodiment. BD's argument essentially goes like this: The preferred embodiment, as illustrated in Figure 9 of the patent, shows two sides of the nozzle key that contact the cuvette, the right side and the left side. Because the right side has a plunger that is interposed between the right side of the nozzle key and the cuvette, there is no direct contact—*i.e.* touching—between the right side and the cuvette. [And] because there is no touching in the preferred embodiment, contact does not require touching.<sup>36</sup>

At this stage of the proceeding, I decline to adopt a construction that does not require touching. Even if BD were correct that the independent claims must be construed to cover the

<sup>&</sup>lt;sup>32</sup> BD's PI motion does not assert infringement under the doctrine of equivalents.

<sup>&</sup>lt;sup>33</sup> Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1348 (Fed. Cir. 2003) (court can adopt "tentative" or "rolling" claim construction to resolve a PI motion).

<sup>&</sup>lt;sup>34</sup> Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1124 (Fed. Cir. 2001) ("In the absence of a special definition of the term 'contact' in the specification, that term should be given its ordinary and accustomed meaning. The district court properly construed the term, according to its ordinary meaning, to mean 'touching."")

<sup>&</sup>lt;sup>35</sup> Bradford Co. v. Conteyor N. Am., Inc., 603 F.3d 1262, 1270-71 (Fed. Cir. 2010).

<sup>&</sup>lt;sup>36</sup> (D.I. 71 at 6-8; D.I. 73 ¶¶ 49-52.)

embodiment illustrated in Figure 9, I have closely studied the patent and the prosecution history, and I don't agree that the right and left sides have to be the hard planar sides called for by claims 1 and 13. In fact, I think it is unlikely that they can be, as contact between the top, left, and right sides of the nozzle key with the cuvette would not define a registered position in the longitudinal (in/out) direction, as required by the claims.<sup>37</sup>

If I had to pick another surface that could be a planar side as called for by the claims, it's at least as likely to be the shoulder described in the specification.<sup>38</sup> . . . In other words, there is a way for the independent claims to cover the preferred embodiment without adopting a strained construction of the term contact. Thus, I am not persuaded by BD's argument that adopting the commonly understood meaning of contact would read out the preferred embodiment.

Adopting a preliminary construction of contact that requires touching, it is clear that the planar sides of the nozzle holder identified by BD do not contact the cuvette. For this independent reason, BD cannot show a likelihood of success on the issue of infringement. <sup>39</sup>

I'll now move on to the second reason I reject BD's position at this stage. Even if BD were correct that the two identified planar sides of the nozzle key and the top of the nozzle contact the cuvette, I am not persuaded that contact with those surfaces holds the nozzle in a defined three-dimensional position and at a registered rotational orientation within the meaning of the claims.

BD's expert acknowledged that there is "tolerance"—*i.e.*, a gap—between the identified planar side surfaces and the flow cell such that if the nozzle holder were moved back and forth, it would contact one or the other wall of the flow cell base. He did not opine

<sup>&</sup>lt;sup>37</sup> (Tr. 15.)

<sup>&</sup>lt;sup>38</sup> See '875 patent, 12:55-59 ("Shoulder 311 on nozzle key 214 is appressed against a surface of cuvette 210 when the nozzle key is fully inserted. This positions the nozzle at a registered position."); see also D.I. 78, Ex. 8 (Slocum Depo) at 121:3-17.

<sup>&</sup>lt;sup>39</sup> Even if contact is not ultimately construed by the Court to require "direct" contact or touching, it is unlikely that the court would adopt any construction of contact that would encompass two components separated by multiple intermediate components and a gap in space.

As mentioned above, BD's PI motion did not assert infringement under the doctrine of equivalents.

that both sides were touching the flow cell base at the same time.<sup>40</sup> In light of that, I agree with Beckman that contacts between the side surfaces identified by BD and the flow cell base (along with contact between the top nozzle surface and the cuvette) do not hold the nozzle in a defined three-dimensional position and rotational orientation.

To be clear, I don't think there is any dispute that there does have to be some tolerance between the nozzle key and the flow cell base so that the key can actually be physically inserted. I do not understand the term contact to read out such a tolerance. In other words, I would not construe the term contact to say there could be no tolerance. But BD has not measured the so-called tolerance between the identified sides of the nozzle holder and the flow cell base, and BD's counsel acknowledged that "nobody" knows the amount of space between them. 41 Accordingly, BD's own expert leaves open the possibility that contact between the sides of the nozzle holder and the flow cell base do not restrict the nozzle to a defined three-dimensional position and rotational orientation.<sup>42</sup> And, indeed, Beckman's expert opined that the nozzle is actually restricted to a defined position by contacts between the cylindrical surface of the nozzle and the V-groove (as well as contact between the top of the nozzle and the cuvette).

BD's position on this issue can also be rejected for the independent reason that the three surfaces identified by BD do not put any constraints on the nozzle holder in the longitudinal (in/out) direction. <sup>43</sup> So those surfaces do not hold the nozzle in a defined three-dimensional position.

Inherent in BD's position is its apparent contention that the claim requirement that the nozzle be "held in said registered position [in a defined three-dimensional position and rotational orientation] by contact between . . . hard planar surfaces of [the] nozzle key and [the] cuvette" does not actually mean that the contact between hard planar surfaces of the nozzle key and the cuvette define the three-dimensional position and rotational orientation of the nozzle. Rather, BD appears to argue that the phrase is met as long as there

<sup>&</sup>lt;sup>40</sup> (D.I. 73 (Second Chalmers Decl.) ¶ 74; Tr. 29.)

<sup>&</sup>lt;sup>41</sup> (Tr. 30.)

<sup>&</sup>lt;sup>42</sup> (Tr. 29-33.)

<sup>&</sup>lt;sup>43</sup> (Tr. 13-15.)

are three planar surfaces that might constrain the free movement of the nozzle holder if it were able to be jiggled around even if contacts with other components actually define the precise three-dimensional position and rotational orientation of the nozzle.

In support of its argument, BD points out that contacts with the claimed planar surfaces cannot be the only things that hold the nozzle key in position. For example, there needs to be something underneath the nozzle key to keep it from falling down.<sup>44</sup> BD also implies that the claimed surfaces do not need to restrict the nozzle key in the longitudinal direction because the claimed nozzle key needs to be able to be pulled out of the device so that it can be cleaned.<sup>45</sup>

BD's briefing did not explicitly say that there was any claim construction issue about what it means to hold something in a defined three-dimensional position and rotational orientation (nor did it proffer a proposed construction), but its counsel suggested during oral argument that there is a "subsidiary claim construction issue" here that might need to be resolved.<sup>46</sup>

I do not think that BD is likely to succeed on its argument, regardless of whether it is viewed as a claim construction argument or an argument about how the accused device operates. Of course, the nozzle key can be removed by pulling it out in the longitudinal direction. And, of course, more than a top and two side surfaces are needed to physically keep the nozzle key from falling down. But the language of the claim, read in view of the specification, suggests that the claimed planar surface contacts must define the three-dimensional position and rotational orientation of the nozzle. And, for the reasons already stated, the record does not support a finding that the surfaces that BD identifies on Beckman's accused device do that.

For all of those reasons, I conclude that BD has failed to demonstrate a likelihood of success on the merits on the issue of infringement. Having so concluded, the Court need not consider the remaining PI factors. The Court should deny the motion for a preliminary injunction.

<sup>&</sup>lt;sup>44</sup> (Tr. 33-34.)

<sup>&</sup>lt;sup>45</sup> (Tr. 13-15.)

<sup>&</sup>lt;sup>46</sup> (Tr. 33.)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C),

Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any

objections to the Report and Recommendation shall be filed within fourteen days and limited to

ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages.

The failure of a party to object to legal conclusions may result in the loss of the right to de novo

review in the district court.

The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R.

Civ. P. 72," dated October 9, 2013, a copy of which can be found on the Court's website.

This Report and Recommendation relies on material set forth in filings that remain under

seal. Accordingly, I am issuing it under seal, pending review by the parties. In the event that any

party contends that portions should be redacted, the parties shall jointly submit a proposed redacted

version by no later than January 14, 2022, for review by the undersigned, along with a motion

supported by a declaration that includes a detailed explanation as to why disclosure of any

proposed redacted material would "work a clearly defined and serious injury to the party seeking

closure." See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., 924 F.3d 662, 672 (3d

Cir. 2019) (quoting Miller v. Indiana Hosp., 16 F.3d 549, 551 (3d Cir. 1994) (internal quotation

marks omitted)). The Court intends to issue a public version of this Report and Recommendation

on or around January 17, 2022.

Dated: January 12, 2022

THE HONORABLE JENNIFER L.

UNITED STATES MAGISTRATE JUDGE

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